

## **REMARKS**

### **REQUEST FOR CONTINUING EXAMINATION**

This Response is being filed with a Request for Continuing Examination under 37 CFR § 1.114 and the fee set forth in § 1.17(e). The Applicants, therefore, request that the Examiner withdraw the finality of the Office Action mailed on 2 November 2006 and consider the arguments presented in this Response and the references cited on the accompanying Supplemental Information Disclosure Statement and supplied herewith.

### **AMENDMENTS TO THE DRAWINGS**

Applicants submitted Drawing Amendments with the Amendment and Response filed on 17 August 2006. Applicants note that the Examiner did not indicate either in the Office Action Summary or in the Detailed Action dated 2 November 2006 whether the drawings filed on 17 August 2006 had been accepted. Applicants respectfully request that the Drawing Amendments filed on 17 August 2006 be accepted and that the Examiner so indicate in the next correspondence.

### **INFORMATION DISCLOSURE STATEMENTS**

With the Office Action mailed on 27 April 2006, the Examiner attached a copy of Form PTO-1449 which the Applicants had submitted with the Information Disclosure Statement filed on 30 December 2005. The Applicants note that the Examiner initialed all U.S. patent documents except those appearing on page 4/9 of Form PTO-1449. The U.S. patent documents that were not initialed have reference designations AA4, AB4, AC4, AD4, AE4, AF4, AG4, AH4, AI4, AJ4, and AK4. The Applicants respectfully request that the Examiner consider these references if he has not already done so and that the Examiner indicate that these references have been considered by returning an initialed copy of page 4/9 of Form PTO-1449 to the Applicants with the next correspondence.

A Supplemental Information Disclosure Statement and Form PTO-1449 are being submitted herewith. The Supplemental IDS lists all foreign patent documents and non-patent literature that was cited earlier but that was not considered. A copy of each foreign patent document and non-patent literature reference is being submitted with the accompanying Supplemental IDS and Form PTO-1449. Applicants believe that no additional separate fee is required for submission of the Supplemental IDS at this time because the Supplemental IDS is being submitted with a Request for Continuing Examination under 37 CFR § 1.114 and the fee set forth in § 1.17(e).

Applicants respectfully request that the Examiner consider all of the submitted art and so indicate by initialing copies of the appropriate Forms PTO-1449 and returning them to Applicants with the next correspondence.

#### CLAIMS

Claims 1-16 are currently pending in the application. All pending claims stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. (WO 01/74274) in view of Hess (WO 92/19310) and in combination with various other references. Applicants traverse these rejections and respectfully submit that none of the cited references, either alone or in combination, render the claimed invention obvious. Applicants request that the Examiner reconsider and withdraw these rejections in view of the remarks presented herein.

A. Rejection of Claims 1-4 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Hess.

As stated in the MPEP:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP 706.02(j), underlining added for emphasis.)

Applicants submit that the Examiner's rejection of claims 1-4 and 13-15 is improper because the Examiner has failed to provide a clear suggestion or motivation that would have led one of ordinary skill in the art to combine or to modify the prior art references in the manner suggested by the Examiner. More importantly, even if the prior art references were combined as the Examiner suggests, the combination would not result in the claimed invention. The combined references do not teach or suggest all of the claim limitations as required for a proper 35 U.S.C. § 103(a) rejection.

The Examiner recognizes that "Palmaz does not disclose the support arranged specifically as having continuous circumferential undulations." (Final Office Action, mailed 2 November 2006, p. 3.) The Examiner continues to assert that "Hess discloses a stent having continuous circumferential undulations (*e.g.* Fig 6A)." (Final Office Action, mailed 2 November 2006, p. 3.) The Applicants respectfully disagree with the Examiner's characterization of Hess. First, Hess does not, in fact, disclose a stent having continuous circumferential undulations. Furthermore, Applicants do not believe that it would be possible to combine the disclosure of Palmaz with the disclosure of Hess at all, let alone in a manner to form the claimed invention.

To illustrate this point more clearly, several figures are reproduced below. The first figure illustrates one embodiment of the Applicants' inventive graft as shown in Figure 12 of the pending application.

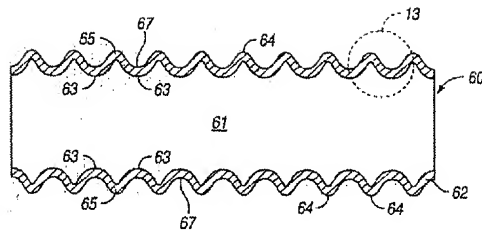
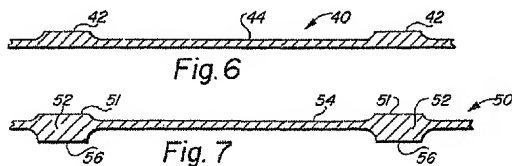


Fig. 12

Applicants' graft

As recited in independent claim 1, the claims of the present application are directed to a graft with a "body member having a plurality of continuous circumferential undulations". Similarly, independent claim 13 recites "a generally cylindrical substrate having a plurality of circumferentially extending continuous undulations with peaks and valleys, patterned along at least a portion of a longitudinal axis of the generally cylindrical substrate." The application explains that "[t]he graft body member 62 has first and second wall surfaces forming luminal and abluminal surfaces of the graft body member and a plurality of corrugations or pleats 64 forming an undulating pattern of peaks 65 and valleys 67 in wall surfaces of the graft body member." (Paragraph [0071].)

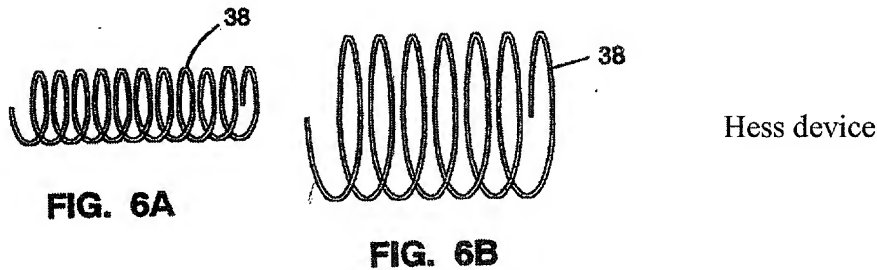
In contrast, and as acknowledged by the Examiner, the body member described in Palmaz et al. (illustrated in Figures 6 and 7 of Palmaz et al. and reproduced below) does not include a plurality of continuous circumferential undulations.



Palmaz et al. graft

The Examiner then suggests combining the Palmaz et al. graft with the Hess device to yield the Applicants' claimed invention. The Examiner asserts that "Hess discloses a

stent having continuous circumferential undulations (e.g. Fig 6A).” (Final Office Action, mailed 2 November 2006, p. 3.) Figures 6A and 6B from Hess are reproduced below.



Contrary to the Examiner’s assertion, the Hess device does not have continuous circumferential undulations. Hess describes the device shown in Figure 6A as follows:

FIG. 6A is a perspective view showing yet another embodiment of a tissue supporting device in the form of a stent-like member in the form of an elongated wire wound spring in a first configuration prior to deformation. (Hess, p. 7, lines 3-7, underlining added for emphasis.)

Hess also states:

FIG. 6A discloses yet another embodiment of a tissue supporting device in the form of a stent-like member in the form of heat-recoverable member 38 which is an elongated wire wound spring-like member including what can be described as a serpentine coil (not shown). (Hess, p.15, lines 14-18, underlining added for emphasis.)

As seen in Figures 6A and 6B from Hess, and as described in the Hess application, the Hess device is a coil or spring-like member.

The combination of Palmaz et al. and Hess does not render the claimed invention obvious. Furthermore, the combination of Palmaz et al. and Hess does not provide each element of the claimed invention. First, the Hess device does not have continuous circumferential undulations. Second, the Hess device does not have a “body member having a plurality of continuous circumferential undulations with peaks and valleys,”

formed in each of the luminal wall and abluminal wall surfaces of the body member.”

Because the Hess device is a spring, it cannot have peaks and valleys in its wall surfaces, as there are no wall surfaces. Additionally, since the Hess device is a spring-like member without walls or wall surfaces, it is unclear how one could combine the teachings of Palmaz et al. and Hess at all, let alone combine them in a manner to yield the claimed invention.

The Examiner has failed to explain how the coil or spring-like device disclosed in Hess provides any teaching or suggestion to provide the continuous circumferential undulations found in the inventive graft. Neither has the Examiner explained how the teachings of Palmaz et al. and Hess could be combined. While a § 103(a) rejection does not require that the inventions of the cited references be physically combinable, the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. (MPEP, § 2145 III, see also MPEP § 2143.01.) In this case, it is not clear how the teachings of Palmaz et al. and Hess could be combined, and if they could be combined, the combination of references still does not provide all elements of the claimed invention.

In summary, the Examiner has failed to show a motivation or suggestion to combine the cited references. Additionally, due to their vastly divergent structures, it is not clear to the Applicants how it would even be possible to combine the teachings of Palmaz et al. with the teachings of Hess as the Examiner has suggested. If it were possible to combine the disclosures of Palmaz et al. and Hess, the combination would not yield the claimed invention, nor render the claimed invention obvious. For at least these reasons, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claims 1-4 and 13-15.

B. Rejection of Claims 5, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Hess, and further in view of Van Schie et al.

Claims 5, 12, and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al, in view of Hess, and further in view of Van Schie et al. (U.S. Patent No. 6,974,471).

As stated in the MPEP:

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ... If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP § 2143.03, underlining added for emphasis.)

As discussed above, the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claims 1 and 13. Since independent claims 1 and 13 are nonobvious in view of the prior art, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 5 and 12, which depend from independent claim 1, and claim 16, which depends from independent claim 13, are, therefore, also nonobvious.

The Examiner relies on Van Schie et al. to provide “at least one suture member integrally extending along the longitudinal axis and through suture holes (*e.g.* Fig. 1).” (Final Office Action, mailed 2 November 2006, pp. 3-4.) Applicants note that the structure referred to by the Examiner in Figure 1 of Van Schie et al. is not, in fact, a suture member integrally extending along the longitudinal axis. Figure 1 of Van Schie et al. shows “a first embodiment of the present invention incorporating an elastic material to provide a reduction in the length of one part of the prosthesis with respect to another.” (Van Schie et al., col. 3, lines 44-47.) Van Schie et al. further explains that “[i]n this embodiment the length reduction arrangement is an elastic material 8 such as a silicone rubber or similar material.” (Van Schie et al., col. 4, lines 25-27.)

Applicants do recognize that other embodiments disclosed in Van Schie et al. do include a suture material, but the disclosed suture material is not “integrally extending along the longitudinal axis and through suture holes” as the Examiner asserts. The suture material that is disclosed by Van Schie et al. is “passed circumferentially around the prosthesis” not longitudinally. (Van Schie et al., col. 4, lines 51-61.)

The rejection of claims 5, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al, in view of Hess, and further in view of Van Schie et al. is improper, and Applicants respectfully request withdrawal of this rejection.

C. Rejection of Claims 6-10 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Hess, in view of Van Schie et al., and further in view of Kula et al.

Claims 6-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al., in view of Hess, in view of Van Schie et al., and further in view of Kula et al. (U.S. Patent No. 6,325,825). Since the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claims 1 and 13, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 6-10, which depend from independent claim 1, are, therefore, nonobvious.

The Examiner recognizes that the combination of Palmaz et al., Hess, and Van Schie et al. “does not disclose the thickness of the undulating regions as less than that of the non-undulating regions.” (Final Office Action, mailed 2 November 2006, p. 4.) The Examiner then asserts that “Kula et al. teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions.” (Final Office Action, mailed 2 November 2006, p. 4.) Applicants respectfully disagree. The thicker ends provided in the Kula et al. stent do not correspond to the varying thicknesses of the undulating and non-undulating regions of the claimed graft. As explained in Kula et al.:



“Other modifications at the ends of the stent 10 may include increasing the thickness of wall of the stent 10 and selectively electropolishing. These modifications protect the artery and any plaque from abrasion that may be caused by the stent ends during insertion of the stent 10.”  
(Kula et al., col. 4, lines 60-64, underlining added for emphasis.)

Kula provides additional thickness and polishing at the ends of the stent in order to protect vessels from damage caused by the stent ends. This smoothing out of the rough ends of the Kula et al. stent does not correspond to having “the wall thickness of the undulating regions [is] less than the wall thickness of the non-undulating regions” as recited in claim 6. Even with the combination of four references, the Examiner has not provided each element of the claims as required for a proper 35 U.S.C. § 103(a) rejection.

With respect to claim 7, the Examiner acknowledges that none of the four combined references teaches or suggests the specific thicknesses recited in claim 7. The Examiner, nonetheless, rejects claim 7 as being obvious. Applicants note that the Examiner has not provided any prior art reference that renders the claimed thicknesses obvious.

With respect to claims 9 and 10, the Examiner acknowledges that none of the four references teaches or even suggests the “generally cruciform-shaped slot pattern” recited in claim 9 or the “generally Y-shaped slot pattern” recited in claim 10. Nonetheless, the Examiner rejects claims 9 and 10 as being obvious. Applicants once again note that the Examiner has failed to provided any prior art reference that would render claims 9 or 10 obvious. Because the Examiner has made these conclusory statements without citing any prior art reference in support of his conclusion, Applicants interpret the Examiner’s statement to be an official notice. Applicants traverse the Examiner’s official notice and request that the Examiner provide evidentiary support for this official notice.

The rejection of claims 6-10 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al., in view of Hess, in view of Van Schie et al., and further in view of Kula et al. is improper, and Applicants respectfully request withdrawal of this rejection.

D. Rejection of Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Hess, and further in view of Banas et al.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al, in view of Hess, and further in view of Banas et al. (U.S. Patent No. 5,749,880). As discussed above, the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claim 1. Since independent claim 1 is nonobvious in view of the prior art, claim 11, which depends from independent claim 1, is also nonobvious.

CONCLUSION

Applicants respectfully request that the Examiner withdraw the rejections of claims 1-16 based on the remarks presented herein. A Supplemental Information Disclosure Statement and a copy of each foreign patent document and each non-patent literature document cited are also being submitted at this time. Applicants submit that the pending claims are patentably distinct from and over the art cited and of record, and respectfully request the application be allowed to issuance.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Response is being filed with a Request for Continuing Examination under 37 CFR § 1.114 and the fee set forth in § 1.17(e). Other than the fess associated with the Request for Continuing Examination, no additional fees are believed necessitated by the filing of this Response. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Donna E. Becker", followed by a horizontal line.

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Reg. No. 44,529

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